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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/585,693

11/09/2006

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EXAMINER

SAJJADI, FEREDOUN GHOTB

ART UNIT

PAPER NUMBER

1633

NOTIFICATION DATE

DELIVERY MODE

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ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/585,693	<b>Applicant(s)</b> YAMASHITA ET AL.	
	<b>Examiner</b> FEREYDOUN G. SAJJADI	<b>Art Unit</b> 1633	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11/13/2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-23 and 25-30 is/are pending in the application.
- 4a) Of the above claim(s) 7-23 and 28-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-6 and 25-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/20/2009</u> . | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Request for Continued Examination***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 13, 2009 that includes a response to the office action dated May 13, 2009, has been entered. Claim 1 and 25-27 have been amended, and claim 2 cancelled. No claims were newly added. Accordingly, claims 1, 3-23 and 25-30 are pending in the application. Claims 7-23 and 28-30 remain withdrawn from consideration, without traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01. Claims 1, 3-6 and 25-27 are under current examination. The claims have been examined commensurate in scope with the elected species of chicken.

#### ***New Claim Rejections - 35 USC § 112- New Matter***

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Applicant's claim amendments have necessitated the following new grounds of rejection.

Claims 25-27 are newly rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art (hereafter the Artisan), that the inventor(s), at the time the application was filed, had

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possession of the claimed invention. 37 CFR §1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Claims 25-27 have been amended to recite 1 mg/egg, 20 mg/egg or 100 mg/egg of the desired protein, respectively. Applicants state that support for the new limitations may be found at pages 9 and 10 of the specification. However, the instant specification appears devoid of such description regarding the concentration of protein per egg. The cited parts of the specification fail to disclose either explicitly or implicitly, protein concentrations per egg, as claimed. The relevant portions of the instant specification at Tables 2-4 (p. 27) discloses protein concentrations in egg yolk expressed as mg/ml.

Thus, at the time the application was filed, an Artisan of skill would not recognize from the disclosure that Applicant was in possession of the protein concentrations per egg, as claimed.

MPEP 2163.06 notes: "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

This is a new matter rejection.

### ***Response & Maintained Claim Rejections - 35 USC § 102***

Claims 25-27 stand rejected under 35 U.S.C. 102(e) as being anticipated by Ransohoff et al. (U.S. Patent Application Publication 2003/0176660; effective filing date Feb. 8, 2002). The rejection set forth on page 5 of the Office action dated March 19, 2008, pp. 3-4 of the Office

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action dated October 3, 2008 and pp. 2-4 of the previous Office action dated May 13, 2009 is maintained for reasons of record.

***The Rejection:***

The claims embrace an egg laid by a transgenic chicken containing not lower than 1 mg/egg, 20 mg/egg or 100 mg/egg of the desired protein respectively.

The structural elements of the transgenic chicken egg, specifically that it possesses various amounts of a desired protein are given patentable weight. The source of the eggs, i.e. the transgenic hen producing the egg, or the method of producing said transgenic hen are not afforded patentable weight, as it is assumed that equivalent transgenic egg products may be obtainable from transgenic hens produced by different methods.

Ransohoff et al. teach compositions containing avian-derived transgenic non-avian antibodies and methods of recovering the compositions from transgenic avian eggs (Abstract). Specifically teaching: "The avian animal is a chicken and the non-avian antibody is a human antibody. For example, a transgenic chicken containing a nucleic acid encoding human antibody molecules under the control of an albumen-specific promoter (e.g. an ovalbumen promoter) produces eggs, which contain the human gene product. A transgenic chicken egg contains at least 10 mg of human antibody per egg. For example, the egg contains 50 mg of human antibody (approximately 2 mg/ml of human antibody)." Paragraph [0005], p. 1.

Therefore by teaching all the limitations of the claims, Ransohoff et al. anticipate the instant invention as claimed.

***Response to Arguments:***

The previous office action indicated that the process steps recited in claim 1 result in transgenic chimeric chickens. Base claim 1 is a product by process claim, wherein the process comprises the method steps of mating a G0 transgenic chimeric bird with any other G0 transgenic chimeric bird or a with a wild type bird. By definition, a G0 chimeric bird carries the transgene in only some of its somatic cells and is not capable of germline transmission of the transgene. Thus crossing a chimeric bird with a wild type bird or a non-related chimeric bird, would further dilute the transgene and cannot result in the production of a true transgenic bird.

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Thus, germline transmission of the transgene is not necessarily achieved, and hence the transgene need not be present in the egg. Moreover, the instant claims are directed to an egg laid by a chicken, containing varying amounts of a desired protein, therefore the features upon which applicant relies (i.e., retroviral specific sequences) are not recited in the rejected claim(s), and not necessarily present. Thus, the claimed chicken of base claim 1 has been interpreted to be a chimeric chicken in view of the method steps recited in the claim, the teachings of the prior art and Applicants' own specification.

Applicants disagree, arguing, that the recitation of a "transgenic bird ... which is obtained as a G1 transgenic bird or an offspring thereof", in claim 1 cannot be ignored. Further arguing that in contrast to a chimeric bird, all cells including germline cells of the claimed G1 birds contain the same genetic information. Therefore, the claimed G1 bird is not chimeric, and would be produced from a GO transgenic chimeric bird, as recited, with a transgene in its germline cells. Accordingly, as long as the GO bird has an exogenous antibody gene in its germline cells, the claimed G1 animal is never a chimera. Applicants' arguments have been fully considered, but are not deemed persuasive.

In response, it should be noted that Applicants' arguments are completely contrary to both the teachings of the prior art and Applicants' own specification. The examiner should not be required to describe the process steps required to produce a transgenic chicken (versus a chimeric chicken), when such is part of Applicants' own invention. While a chicken harboring a transgene in some of its cells is technically "transgenic", the distinction between a chimeric and a true transgenic chicken (i.e. one where the transgene is present in all its cells in homozygous form, and useful for establishing a transgenic line) cannot be blurred. Applicants are directed to a review by Mozdziak et al. (Develop. Dynamics 229:414-421; 2004), describing technologies that have been used to generate transgenic chickens and the challenges involved in the complex and laborious endeavor (Abstract and third column, p. 414). Fig. 3, p. 417, depicts the general steps in the production and establishment of a line of transgenic chickens, that include the production of G1 progeny, where some of the progeny inherits the transgene. However, most of the G1 progeny is still wild type and only a few are chimeric with respect to the transgene and require additional crosses to produce both G2 and G3 progeny birds, and even then only some of the G3

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progeny will be homozygous individuals that would require further crosses to establish and characterize a usable line of birds. Applicants' own specification describes the generation of G2 and G3 (second and third generation) birds from reproductive lineage chimeric individuals to produce an individual whose somatic cells in the whole body contain the transgene (lines 19-27, p. 12). Therefore, in view of the process steps recited in base claim 1, the resulting product has been correctly interpreted as a chimeric bird. All the method steps have been considered in determining that the resulting product must necessarily be at best a chimeric chicken. If all words in the claim must be considered, then the method steps cannot be ignored. Thus, in keeping with Applicants' previously cited case law (*Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir 1987)), every element in the claim has been considered in determining that the claimed product must be a chimeric or a transgenic chimeric chicken.

Therefore, the rejection is maintained for reasons of record and the foregoing commentary.

### ***Response & Maintained Claim Rejections - 35 USC § 103***

Claims 1 and 3-6 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sang et al. (U.S. Patent Application Publication 2005/0273872), as evidenced by Kamachi et al. (Development 125:2521-2532; 1998), in view of Rapp, J. (U.S. Patent Publication No. 2002/0108132, effective filing date Feb. 2, 2001). Applicants' cancellation of claim 2 renders its rejection moot. The rejection set forth in the Office action dated October 3, 2008, and pp. 4-6 of the previous Office action dated May 13, 2009 is maintained for reasons of record. It should be noted that Applicants' cancellation of "Moloney murine leukemia virus" as a limitation of base claim 1 obviates the reference of Rapp et al.

### ***The Rejection:***

The claims embrace G1 and G2 transgenic chickens or an offspring thereof, comprising a replication-deficient retroviral vector derived from Moloney murine leukemia virus, coding for a desired protein, or an antibody.

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With respect to claims directed to the G1 (and G2) transgenic chicken, they are determined to be a product-by-process claims. The structural elements of the transgenic chicken, specifically that it possesses a replication defective retroviral vector encoding a desired protein are given patentable weight. The recitation of a process limitation in claim 1 is not viewed as positively limiting the claimed product absent a showing that the process of making imparts a novel or unexpected property to the claimed transgenic chicken product, as it is assumed that equivalent transgenic chicken products are obtainable by multiple routes. The recitation "obtainable by" is not considered to limit the claimed transgenic chicken because the G1 and G2 transgenic chickens may be obtained by other reproductive means. The burden is placed upon the applicants to establish a patentable distinction between the claimed and referenced products. The method in which the transgenic chickens were produced is immaterial to their patentability. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). See also MPEP §2113.

Sang et al. describe the generation of transgenic avians and the expression of transgene encoded protein within the avian egg (Title and Abstract). Replication defective vectors, such as ALV and other lentiviruses are described in paragraph [0013], on p. 2 and paragraph [0017], p. 3. Lentiviruses are described as a subgroup of the retroviruses (paragraph [0015], p. 3). Sang et al. specifically disclose obtaining fertile hen's eggs containing developing chick embryos at developmental stages X-XIII ; and injection of VSV-G pseudotyped lentiviral vector into the subgerminal cavity below the embryo (Experiment 1, paragraph [0064], p. 5), to produce G0 transgenic chickens (paragraph [0090], p. 7).

Stage 13 chick embryos include the gastrula stage, i.e. up to and including 48 hours; such is evidenced by Kamachi et al. in describing the expression of the lens-specific crystallin gene in the developing chicken (first column, under summary; limitation of claims 2 and 3).

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Germ line transmission from G0 males and breeding by crossing to stock hens and screening their G1 offspring is described in paragraph [0092], p. 7. The analysis of G1 transgenic birds and transmission to G2 from the founder birds is described in paragraphs [0093-0095], p. 7 (limitation of claim 6). Transgene expression in G1 and G2 transgenic birds is disclosed in paragraph [0096], pp. 7-8. Sang et al. further state that the transgene material may encode any of a large number of proteins, and may include sequences encoding antibodies (paragraph [0030], p. 4; limitation of claim 4).

While Sang et al. do not describe the production of transgenic chimeric chicken using a retroviral vector derived from Moloney murine leukemia virus, such was known in the prior art.

Rapp et al. describe transgenic chickens (Abstract and p. 4, paragraph [0041]), transformed with recombinant retroviral expression vectors, including a Moloney murine leukemia virus-derived vector (p. 5, paragraphs [0052 and 0054]; p. 9, paragraphs [0094-0095]; pg 16, [0158]), wherein said vectors comprise a gene encoding [chimeric] antibodies comprising human immunoglobulin constant domains, single-chain antibodies, and antibody fragments and/or from birds or mice (pp. 6-7, paragraphs [0062-0068]; p. 15, paragraph [0151]; p. 16, paragraph [0161]) operably linked to, for example, to a chicken oviduct-specific promoter such as ovalbumin (p. 9, paragraph [0090]; p. 16, paragraph [0159]) and Example 5, p. 19.

The teachings of Sang et al., and Rapp et al. are all directed to the production of transgenic chickens using retroviral-derived vectors. Therefore, it would have been *prima facie* obvious for a person of ordinary skill in the art to combine their respective teachings to utilize the Moloney murine leukemia virus-derived vector of Rapp et al., in the method of Sang et al. as instantly claimed, as a matter of design choice, with a reasonable expectation of success, at the time of the instant invention. Said design choice amounting to combining prior art elements according to known methods to yield predictable results. Applicants should note that the *KSR* case forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. *KSR International Co. v. Teleflex Inc.*, 550 U.S.-, 82USPQ2d 1385 (2007).

***Response to Arguments:***

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Applicants disagree, arguing the Office Action has improperly ignored the recitation in claim 1 that the microinjection is "at a stage except for and after the blastodermic stage just after egg laying". Applicants' arguments have been fully considered, but are not deemed persuasive. As specifically indicated in the previous Office actions, and recited above, Stage XIII chick embryos include the gastrula stage, i.e. up to and including 48 hours; such is evidenced by Kamachi et al. in describing the expression of the lens-specific crystallin gene in the developing chicken (first column, under summary).

Applicants argue the developmental stages of chicken embryos in Sang and Kamachi are different from each other, because in Kamachi, the developmental stages are defined according to Hamburger and Hamilton (1951), and the developmental stages in Sang are defined according to Eyal-Giladi & Kochav (1976) which teaches that the "[f]ourteen developmental stages preceding Hamburger and Hamilton's stage 2 have been studied from live material..." (see Abstract of Eyal-Giladi). Accordingly, since Hamburger and Hamilton's stage 2 is 7 hours after the start of incubation, virus infection at stages of X-XIII in Sang means that Sang infects viruses 7 hours after the start of incubation, at the latest. Concluding the developmental stages described in Sang are distinct from Kamachi.

In response, it is noted that Applicants' analysis is flawed in several respects. Applicants' arguments are based on a single line taken out of context, from the Abstract of Eyal-Giladi, that states fourteen developmental stages preceding Hamburger and Hamiltons' stage 2 have been studied. However, the statement by Eyal-Giladi referring to further refinement of earlier developmental stages does not negate or preclude the established and accepted stages in chick development. The statement does not ignore the accepted developmental stages as earlier established with respect to blastoderm and gastrula development. In fact, the Abstract of Eyal-Giladi concludes by suggesting that the term germ be used for all early stages, and the term blastoderm applied from stage VI onward. Thus, a person of ordinary skill in the art reading Eyal-Giladi as a whole would not ignore the established developmental stages of chick development. Moreover, in Experiment 2, paragraph [0065], Sang et al. describe the introduction of vector into the sub-blastodermal cavity. Thus, taking Eyal-Giladi's suggested terminology into consideration, the blastoderm must necessarily be at stage VI and beyond, and not earlier than

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stage 2 as argued by Applicants. As indicated on page 56 of Hamburger, stage 13 covers 48-52 hours.

Applicants repeat their argument that Sang, teaches away from the presently claimed invention because Sang explicitly teaches that the use of a delivery vector derived from MMLV during development. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., MMLV) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicants have argued limitations specifically deleted from the claims. Moreover, such arguments have been previously addressed, and by delivering the vectors of Sang et al. at the developmental stages suggested by the authors, a person of ordinary skill in the art would have a reasonable expectation of success in expressing a desired protein.

Applicants argue, that based on the disclosures in Sang and Rapp, one of ordinary skill in the art would not have had a reasonable expectation of success of obtaining as much as, for example, 1.5-1.6 mg/ml of antibody expressed in the blood, and as much as 0.33-0.57 mg/ml expressed in egg yellow and egg white, as achieved by the present invention (see Tables 1-4).

Such is not found persuasive, because the instant claims do not require the production of proteins of a specified concentration (or "as much"). The claims are directed to a transgenic chicken whose genome comprises a replication-deficient retroviral vector encoding an antibody. Moreover, any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected. *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Further, the fact that Applicants have recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Enhanced transgene expression would naturally flow from the process of

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making a transgenic chicken according to the stage XIII embryos, that include the gastrula stage, because such is a biological phenomenon, inseparable from the organism.

Further, as previously indicated, while Sang et al. state that it is essential that any viral vector used for production of transgenic birds does not exhibit gene silencing, the reference to Moloney murine leukemia virus is from the teachings of Jahner et al. published in 1982, directed to de novo methylation and expression of retroviral genomes during mouse embryogenesis (paragraphs [0016 and 0129]. Therefore, the teachings of Jahner et al. are not necessarily extendable to chickens, especially given the body of subsequent publications with regard to using retroviral vectors in chimeric or transgenic birds.

Thus, the rejection is maintained for reasons of record and the discussion set forth above.

#### ***Reinstated Claim Rejections - 35 USC § 102***

Claims 1 and 3-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Sang et al. (U.S. Patent Application Publication 2005/0273872), as evidenced by Kamachi et al. (Development 125:2521-2532; 1998), as previously set forth in the Office action dated March 19, 2008. Applicants have amended base claim 1 to remove the limitation: "wherein the replication-deficient retroviral vector is derived from Moloney murine leukemia virus". Accordingly, the rejection has been reinstated.

The claims embrace G1 and G2 transgenic chickens or an offspring thereof, comprising a replication-deficient retroviral vector coding for a desired protein, or an antibody.

With respect to claims directed to the G1 (and G2) transgenic chicken, they are determined to be a product-by-process claims. The structural elements of the transgenic chicken, specifically that it possesses a replication defective retroviral vector encoding a desired protein are given patentable weight. The recitation of a process limitation in claims 1 and 7 are not viewed as positively limiting the claimed product absent a showing that the process of making imparts a novel or unexpected property to the claimed transgenic chicken product, as it is assumed that equivalent transgenic chicken products are obtainable by multiple routes. The recitation "obtainable by" is not considered to limit the claimed transgenic chicken because the

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G1 and G2 transgenic chickens may be obtained by other reproductive means. The burden is placed upon the applicants to establish a patentable distinction between the claimed and referenced products. The method in which the transgenic chickens were produced is immaterial to their patentability. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). See also MPEP §2113.

Sang et al. teach the generation of transgenic avians and the expression of transgene encoded protein within the avian egg (Title and Abstract). Replication defective vectors, such as ALV and other lentiviruses are taught in paragraph [0013], on p. 2 and paragraph [0017], p. 3. Lentiviruses are described as a subgroup of the retroviruses (paragraph [0015], p. 3). Sang et al. specifically teach obtaining fertile hen's eggs containing developing chick embryos at developmental stages X-XIII ; and injection of VSV-G pseudotyped lentiviral vector into the subgerminal cavity below the embryo (Experiment 1, paragraph [0064], p. 5), to produce G0 transgenic chickens (paragraph [0090], p. 7).

Stage 13 chick embryos include the gastrula stage, i.e. up to and including 48 hours; such is evidenced by Kamachi et al. in describing the expression of the lens-specific crystallin gene in the developing chicken (first column, under summary; limitation of claims 1 and 3).

Germ line transmission from G0 males and breeding by crossing to stock hens and screening their G1 offspring is described in paragraph [0092], p. 7. The analysis of G1 transgenic birds and transmission to G2 from the founder birds is described in paragraphs [0093-0095], p. 7 (limitation of claim 6). Transgene expression in G1 and G2 transgenic birds is taught in paragraph [0096], pp. 7-8. Sang et al. further teach that the transgene material may encode any of a large number of proteins, and may include sequences encoding antibodies (paragraph [0030], p. 4; limitation of claim 4).

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Therefore by teaching all the limitations of the claims, Sang et al. anticipate the instant invention as claimed.

### ***Conclusion***

#### **No claims are allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FEREDOUN G. SAJJADI whose telephone number is (571)272-3311. The examiner can normally be reached on 6:30 AM-3:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Fereydoun G Sajjadi/  
Primary Examiner, Art Unit 1633